

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re PATENT APPLICATION OF

MÖCKEL *et al.*

Group Art Unit: 1634

Appl. No.: 09/813,919

Examiner: J. EINSMANN

Filed: March 22, 2001

Title: NUCLEOTIDE SEQUENCES ENCODING THE DAPC GENE AND PROCESS FOR THE PRODUCTION OF L-LYSINE

December 24, 2002

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**AMENDMENT PURSUANT TO 37 C.F.R. § 1.111**

Hon. Commissioner of Patents  
Washington, D.C. 20231

Sir:

This is in response to the official action dated September 25, 2002, wherein the claims were variously rejected under 35 U.S.C. §112, first and second paragraphs, and 35 U.S.C. §§102(a) and (b). The applicants respectfully traverse in view of the following amendment and remarks.

**I. AMENDMENT**

*Prior to further action on the merits, please amend the application as follows.*

**IN THE CLAIMS**

*Please cancel claims 1-5, without prejudice.*

*Please amend claims 6, 7, and 15 as follows.*

6. (Amended) Sector pXT-dapCexp having the restriction map shown in Figure 2 and deposited as DSM 13254 in *Corynebacterium glutamicum*.

7. (Amended) A coryneform bacterium comprising the vector of claim 6.

15. (Amended) An isolated polynucleotide consisting of at least 20 consecutive nucleotides selected from SEQ ID NO:1 or the full complement thereof, wherein said isolated polynucleotide is a hybridization probe for the detection or isolation of a polynucleotide encoding a N-succinylaminokeptopimelate transaminase.

*Please cancel claim 18, without prejudice.*

*Please amend claims 19-21 as follows.*

19. (Amended) An isolated DNA encoding a protein comprising the amino acid sequence of SEQ ID NO:4, wherein said protein has N-succinylaminokeptopimelate transaminase.

20. (Amended) An isolated DNA comprising nucleotides 91 to 1191 of SEQ ID NO:3.

21. (Amended) A coryneform bacterium comprising the isolated DNA of claims 19 or 20.

*Please add the following new claims 22-25.*

--22. The isolated DNA of claim 19 or 20, wherein said isolated DNA is isolated from a coryneform bacterium.

23. An isolated coryneform bacterium comprising a DNA encoding a protein comprising the amino acid sequence of SEQ ID NO:4, wherein said protein has N-succinylaminoketopimelate transaminase activity.

24. An isolated coryneform bacterium comprising the DNA of nucleotides 91 to 1191 of SEQ ID NO:3.

25. An isolated polynucleotide consisting of at least 15 consecutive nucleotides selected from SEQ ID NO:1, wherein said isolated polynucleotide is a primer in a polymerase chain reaction to produce a polynucleotide encoding a N-succinylaminoketopimelate transaminase.--

## **II. REMARKS**

### **Preliminary Remarks**

Upon entry of the foregoing amendment, claims 6, 7, 15, 19-25 will be at issue. Support for new claims may be found throughout the specification (including the claims) as originally filed. Specifically, support for new claim 22 may be found in canceled claim 18. Support for new claim 23 may be found at page 11, lines 10 and 11 of the specification. Support for new claim 24 may be found at page 11, line 36 to page 12, line 4. Support for new claim 25 may be found at page 4, lines 11-19. No new matter is believed to have been introduced herein by the foregoing amendment.

Pursuant to the examiner's comments in Section 12 of the official action dated September 25, 2002, the applicants have enclosed herewith a certified translation of the German priority document (Application No. 100 14 546.9, filed March 23, 2000).

Attached is a marked-up version of the changes made to the claims by the current amendment. The attached Appendix is captioned **“Version with markings to show changes made”**.

**Patentability Remarks**

**35 U.S.C. §112, Second Paragraph**

The examiner, in Sections 5 and 6 of the official action rejected claims 2, 4-7 and 18-21 under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter that the applicants regard as their invention.

The examiner stated that “[a] broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired.” Therefore, with respect to claim 2, the examiner noted that the claim is directed to a broad recitation, “the polynucleotide according to claim 1,” as well as a “preferably recombinant DNA replicable in coryneform bacteria,” which is the narrower statement of the range/limitation. It is the examiner’s position that claim 2 is unclear in that whether the “preferably” portion of the claim is a limitation of the claim. The examiner stated that removal of the term, “preferably,” would negate the issue.

The examiner rejected claims 2, 4 and 5 in that the use of the language “replicable” is allegedly indefinite. Essentially, the examiner stated that “because the ability of a recombinant DNA to replicate is a latent characteristic and the claims do not set forth the criteria by which to determine this capability.”

With respect to claim 6, the examiner asserted that the phrase “in particular” renders the claim indefinite because it is unclear whether the limitations following the phrase are part

of the claimed invention. Regarding claim 7, the examiner stated that the language recitation “the *zwa1* gene” is indefinite because such a designation is allegedly arbitrary.

Claims 18-21 were also rejected as allegedly being indefinite. The examiner asserted that language “originating from coryneform bacteria” because it is not clear what it means for a DNA to have originated from a bacteria. The examiner also stated that claims 18-21 are indefinite because they allegedly do not make clear the connection between the N-succinylamionketopimelate transaminase that is encoded by the DNA and the amino acid sequence shown in SEQ ID NO: 2 that are both recited in claim 18. The examiner stated further that the recitation “the amino acid sequence shown in SEQ ID NO: 2 in position 209” in claim 18 is not clear.

Regarding claim 19, the examiner stated that the claim “is indefinite because it is not clear if the sequences referred to in parenthesis are meant to be limitations to the claim, and if so, how they are meant to limit the claim.” With respect to claim 20, the examiner asserted that the recitation “the replacement of L-proline with L-leucine in position 209” allegedly lacks proper antecedent basis because the claim does not previously refer to such a specific replacement. The claim is allegedly further indefinite over the recitation “cytosine in position 716” because the claim does not set forth what sequence’s position 716 is being referenced. The claim has not previously recited any nucleic acid sequence. Furthermore, the claim recites “as shown in SEQ ID NO: 3” but it is not clear what is being shown in SEQ ID NO: 3. That is, it is not clear if this is intended to limit the instant claim to a DNA comprising SEQ ID NO: 3, or if SEQ ID NO: 3 is merely an example of a DNA that has a cytosine at position 716.

The applicants respectfully traverse and submit that the foregoing rejections based upon 35 U.S.C. §112, second paragraph are now moot in view of the foregoing amendment to the claims. Specifically, the rejection of claims 1-5 and 18 is now moot in that these claims

have been canceled (without prejudice) and any replacement claims that may appear do not have the issues referred to by the examiner. As to the rejection of claims 6, 17, and 19-21, the applicants submit that foregoing amendment has also rendered moot the present rejection of said claims, *i.e.*, the applicants have amended the claims in a manner similar to the examiner's suggestions.

In view of the foregoing, the applicants submit that claims are neither vague nor indefinite and thus request that the rejection based upon 35 U.S.C. §112, second paragraph be withdrawn and not be extended to the new claims.

35 U.S.C. §112, First Paragraph

Claims 1-7 and 15 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Essentially, it is the examiner's position that while claims 1-7 and 15 encompass a large genus of polynucleotides of polynucleotides having hundreds of thousands of members, that genus is only represented in the specification by SEQ ID NO: 1 and polynucleotides encoding SEQ ID NO: 2 and by SEQ ID NO: 3 and polynucleotides encoding SEQ ID NO: 4. Thus, the applicants have (allegedly) express possession of a limited number of species in a genus which comprises hundreds of millions of different possibilities.

Further, regarding written description, the examiner asserted that claims 1-7 and 15 encompass nucleic acid sequences different from those disclosed in the specific SEQ ID NO.'s, which include modifications permitted by the percentage identity language for which no written description is provided in the specification. In addition, the claims encompass nucleic acids that have only 15 nucleotides in common with a nucleic acid that has 70% homology to either a polynucleotide encoding a polypeptide containing instant SEQ ID NO: 2

or which encode a polypeptide that have 70% homology to instant SEQ ID NO: 2. These nucleic acids can have these 15 nucleotides embedded in any other nucleic acid sequence.

The examiner stated that while the specification provides examples of polynucleotides encoding two particular N-succinylamionketopimelate transaminases, but the specification does not provide any description of other N-succinylamionketopimelate trasnaminase from other species of bacteria or other organisms. The specification does not contain any written description of how the enzymes taught in the specification (SEQ ID NO: 2 and SEQ ID NO: 4) can be modified but still result in functional N-succinylamionketopimelate transaminases.

The examiner asserted further that at the time of filing, there is no record or description (in the specification) that would demonstrate conception of any polynucleotides encoding polypeptides modified by addition, insertion, deletion, substitution or inversion with the disclosed sequences encoding polypeptides possessing one or more amino acid differences from SEQ ID NO: 2 or SEQ ID NO: 4 such that a different amino acid sequence is encoded which is a functional N-succinylamionketopimelate transaminases.

Claims 1-7, 15, 18 and 21 were also rejected under 35 U.S.C. § 112, first paragraph, as being broader than the enabling disclosure. Specifically, while being enabled for polynucleotides encoding SEQ ID NO: 2 or SEQ ID NO: 4, the specification allegedly does not reasonably provide enablement for (a) polynucleotides that encode polypeptides having 70% homology to SEQ ID NO: 2, (b) polynucleotides having 70% homology to a polynucleotide encoding SEQ ID NO: 2, polynucleotides comprising at least 15 successive nucleotides of (a) or (b), or polynucleotides encoding a N-succinylamionketopimelate transaminases with any other amino acids in position 209 of SEQ ID NO: 2 or SEQ ID NO: 4.

Claims 6 and 7 were rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make

and/or use the invention. Specifically, the examiner is require the submission of s declaration of biological deposit.

The applicants respectfully traverse and submit that the foregoing rejections based upon 35 U.S.C. §112, first paragraph are now moot in view of the foregoing amendment to the claims. Specifically, the rejection of claims 1-5 and 18 is now moot in that these claims have been canceled (without prejudice) and any replacement claims that may appear do not have the issues referred to by the examiner. As to the rejection of claims 6, 17, and 19-21, the applicants submit that foregoing amendment has also rendered moot the present rejection of said claims, i.e., the applicants have amended the claims similar to the examiner's suggestions. Further to the rejection of claims 6 and 7, the applicants have enclosed herewith a declaration of biological deposit.

In view of the foregoing, the applicants submit that claims are neither vague nor indefinite and thus request that the rejection based upon 35 U.S.C. §112, first paragraph be withdrawn and not be extended to the new claims.

35 U.S.C. §102(b)

Claims 1-7 and 15 were rejected under 35 U.S.C. §102(b) as allegedly being anticipated by US Patent No. 4,954,441. Essentially, it is the examiner's position that as currently presented, the foregoing claims encompass the disclosure of the cited US patent.

The applicants respectfully traverse and submit that as amended herein claim 6, 7, and 15 are novel over the cited patent in that they are directed to specific polynucleotide sequence or portions thereof.

In view of the foregoing, the applicants request the withdrawal of the rejection based upon 35 U.S.C. §102(a).



35 U.S.C. §102(b)

Claims 1-3, 5 and 15 were rejected under 35 U.S.C. § 102(a) as being anticipated by (WO 01/00843).

Pompejus *et al.* teach an isolated acid comprising a polynucleotide containing at least 15 successive nucleotides of the polynucleotide encoding SEQ ID NO: 2. Specifically, SEQ ID NO: 127 taught by Pompejus *et al.* has 100% identity with nucleotides 1-765 of instant SEQ ID NO: 1. Pompejus *et al.* teach *Corynebacterium glutamicum* comprising the polynucleotide (p. 8, line 19), and thus the sequence is replicable in coryneform bacteria. Pompejus *et al.* teach cDNAs, DNAs or RNAs (p. 6, line 12), as well as hybridization probes (p. 6, lines 14-15). The nucleic acid taught by Pompejus *et al.* would hybridize to SEQ ID NO: 1. Pompejus *et al.* teach vectors comprising the isolated polynucleotide (p. 8, lines 1-5). Thus, the teachings of Pompejus *et al.* meet the limitations of each of the rejected claims.

In view of the foregoing amendment to the claims, claims 1-3 and 5 have been canceled herein and claim 15 has been amended to be directed to a specific nucleotide sequence, the applicants submit that the cited international application does not anticipate the presently claimed invention.

Claims 1, 2, 5 and 6 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Mahairas *et al.* (GenBank Accession AQ522445, GI: 4769479, May 1999).

It is the examiner's position that Mahairas *et al.* teach an isolated polynucleotide comprising at least 15 successive nucleotides of the complement of SEQ ID NO: 1. Namely, nucleotides 96-114 of the sequence taught by Mahairas *et al.* are identical to the complement of nucleotides 1207-1225 of instant SEQ ID NO: 1. The polynucleotide sequence taught by Mahairas *et al.* is within a pBACe3.6 vector. The polynucleotide sequence taught by Mahairas *et al.* would hybridize to instant SEQ ID NO: 1 under some stringency conditions, albeit very low stringency.

In response, the applicants submit that the rejection of claims 1, 2, and 5 is now moot in that these claims have been canceled herein. With respect to claim 6, the applicants submit that as amended herein, the cited document cannot, as a matter of law, render the present claim unpatentable.

In view of the foregoing, the applicants request the withdrawal of the rejections based upon 35 U.S.C. §102(b).

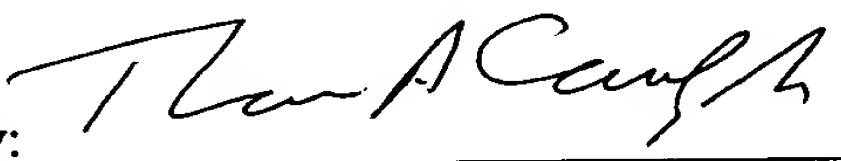
### **III. CONCLUSION**

In view of the foregoing, the claims are now believed to be in form for allowance, and such action is hereby solicited. If any point remains in issue that the examiner feels may be best resolved through a personal or telephone interview, the examiner is **strongly urged** to contact the undersigned at the telephone number listed below.

All objections and rejections having been addressed, it is respectfully submitted that the present application is in a condition for allowance and a Notice to that effect is earnestly solicited.

Respectfully submitted,

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Enclosure: Appendix